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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,067	08/16/2001	David B. Weiner	UPN-3695	4038
34136	7590	12/15/2004	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 12/15/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,067

Applicant(s)

WEINER ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' response filed 9/23/04 has been received and entered.
2. Claims 1, 2, 5-34 are pending. Applicant's elected CD156 promoter in Paper No. 9.
3. The 1.132 declaration by Dr. David B. Weiner filed 10/5/04 has been entered and considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2 and 6-8, 18-24, 29 and 30 remain rejected and amended claims 9-12, 14-17 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record set forth in the previous office action of 3/24/04. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Arguments

Applicant's arguments filed 9/23/04 have been fully considered but they are not persuasive. Applicants amendment of claims to recite that the macrophage specific promoter is from a human gene does not obviate the rejection because the claimed invention still encompasses a promoter of any gene that is specific to a human macrophage cell and the specification as filed does not provide sufficient description of the structure and identifying characteristics of a sufficient number of species of the genus claimed. Applicants' arguments that office failed to provide evidence that the claims fail to satisfy the written description requirement are not persuasive because the office clearly discussed that what was discussed in the specification and did not represent sufficient number of species of the genus. It is emphasized that the claimed invention encompasses promoter sequence of any gene that is specifically expressed in a macrophage cell which has a specialized function and the genes that will be specifically expressed in this cell will be very different from each other and therefore, the

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genus of macrophage specific promoter will represent multiple subgenera that will have unrelated structure and function. For example, in the instant case the species disclosed in the specification represent four different genes that have very different biological function and nucleotide structure and do not share common core structure. If there is any such core structure have neither disclosed nor have addressed in there arguments as to what is that core structure that would be common to different members of the genus. Applicants' arguments that they have described functional characteristic as:

Applicants have defined the *functional characteristic* of a "macrophage specific promoter." The structural characteristic is that the macrophage specific promoter comprises nucleotide bases that allows a nucleotide sequence to confer macrophage specific expression in a human. The amendment to the claims that recites "macrophage

Such functional characteristics do not and cannot differentiate one species from the other species or from other subgenera or subspecies because all of them will have this functional characteristics. Therefore, functional characteristic cannot be an identifying characteristic. It is noted that except for arguing applicants have not provided any substantial evidence to show that they had possession of a sufficient number species of the genus claimed. Applicants have also submitted a three sentence declaration from the inventor which does not provide any evidence except for making a conclusory remark. Applicants' arguments that applicants are not claiming macrophage specific promoter per se are not persuasive to obviate the rejection because while the applicants do not claim the promoter they are required to teach sufficient number of species to show their possession of the broad genus claimed.

It is therefore maintained that the limited information in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of macrophage specific promoters for the broad genus claimed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

6. Claims 1-2 and 5-8 remain rejected and newly presented claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an method of delivering a protein to a macrophage cell or a cell of macrophage derived lineage in vitro or in vivo, comprising intramuscular administration of a plasmid DNA molecule wherein a

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nucleotide sequence encoding the protein is operably linked to a macrophage specific promoter and a polyA signal that is functional in macrophage cell or a cell of macrophage derived lineage, wherein said macrophage specific promoter is selected from the list a catalase promoter, a CD156 promoter, a M-CSFR promoter, a p73 promoter and an FcγRI promoter, wherein said plasmid DNA molecule is taken up by a macrophage cell or a cell of macrophage derived lineage and wherein said nucleotide sequence is expressed to produce said protein in said macrophage cell or said cell of macrophage derived lineage, not reasonably provide enablement for other embodiments for reasons of record set forth in the previous office action of 3-27-03 and 8-8-03 and as discussed below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 9-31 and 34 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office action of 3-27-03 and 8-8-03.

Response to Arguments

Applicant's arguments filed 9-23-04 have been fully considered but they are not persuasive to obviate the rejections. Applicants' arguments that office is not following proper practice as required in MPEP 2164.04 are misplaced because the office action has provided arguments based on state of the art and sound scientific reasoning and applicants have not provided any substantive evidence to indicate that the discussion in the office action is in error. Applicants' arguments that the references used in the office action are irrelevant and non-analogous are not persuasive and are rather misplaced because these references discussed the state of the art of delivering a gene of interest to a target cell in vivo for therapeutic purposes and neither the specification nor the arguments or declaration of record provide any evidence that in view of the unpredictability of the state of the art an artisan by following the teachings of the specification could practice the claimed method without undue experimentation. Applicants argue what is lacking in Crystal or Anderson or Clay references, however it misses the point that the issue at hand is not what these references teach rather the issue is whether the specification was enabling for the claimed invention in view of the unpredictability of the state of

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the art of targeted gene delivery and gene therapy as discussed by these references. It is emphasized and reiterated that neither applicants argument nor the specification addresses the unpredictability issues discussed in the office action and in these cited reference that are relevant and important for practicing the claimed invention commensurate with the scope of the claims.

Therefore, the rejection of record is maintained.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-17 are indefinite because it is unclear as to what is meant by the term "a site on said individual's body that is proximal to said lymph node". The metes and bounds of the claimed invention are not clear because the word "proximal" is relative and an artisan would not know what is encompassed by the claimed invention.

Applicants arguments that those of ordinary skill would readily know and could identify a site on an individual's body are not persuasive because while the literal meaning of proximal is provided by a dictionary, for what would be a proximal site for delivering a gene to lymph node will not be readily known to an ordinary skill in the art because it is unclear as to how close or very near will be very near.

The indefiniteness rejection of claim 12 is withdrawn in view of applicants' amendment, however, a new indefiniteness rejection is set forth because as amended, claim 12 does not further limit the invention of claim 9.

9. As noted in the previous office action, Claims 1-2 5-8 and the new claims 32-32 would be allowable if written in conformation with the scope of enablement rejection set forth above.

10. No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (571) 273-8300. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.
Primary Examiner



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER